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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,414	09/18/2001	Nancy L. Parenteau	56001/02021	1042

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EXAMINER	
PREBILIC, PAUL B	
ART UNIT	**PAPER NUMBER**
3774	

MAIL DATE	DELIVERY MODE
12/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

CT

Office Action Summary	Application No.	Applicant(s)	
	09/955,414	PARENTEAU ET AL.	
	Examiner	Art Unit	
	Paul B. Prebilic	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 7-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 7-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 25, 2007 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3, and 7-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The new ranges of "inserting at least a first cultured connective tissue construct" and "grafting at least a second cultured connective tissue construct" lacks original support. It is noted that 37 CFR 1.114 does not allow the introduction of new matter as is done in the continuation-in-part practice.

In addition, the combination of a step of inserting at least a cultured connective tissue into the opening where at least a second construct is used to close the opening

lacks original support as well. It is noted that the Applicant failed to point out support for the new claim limitations even though that was required by the previous Office action; see the fourth paragraph of the "Conclusions" section of the April 25, 2007 Office action.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, and 7-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoval (WO 99/04720) in view of Murphy et al (WO 00/29553) and Lambrecht et al (US 7,220,281). Stoval discloses a method of forming an opening in an annular fibrosis (see page 10, line 1 to page 11, line 12 and Figure 2), removing at least a portion of the nucleus pulposis (see *supra*), and grafting a cultured connective tissue construct to close the opening (see page 2, lines 10-18, page 3, lines 7-14, and page 4, lines 10-15). The layer of extracellular matrix as claimed is met by the layer of extracellular matrix material that is inherently present around the cultured cells of Stoval.

However, Stoval fails to clearly disclose using a bioremodelable construct in the method as claimed. Murphy teaches that it was known to make bioremodelable graft constructs without exogenous matrix components or synthetic members in the repair a variety of tissues; see pages 1-19 and claim 19 thereof and see the present specification and the paragraph bridging pages 5 and 6. Lambrecht teaches that is was known to both insert a first repair material into the opening and to graft a second

material to close the opening as claimed; see Figure 26, column 19, line 18 et seq. and the paragraph bridging columns 26 and 27.

Particularly, Murphy teaches the use of bioremodelable constructs as replacements or improvements over those constructs of the art that relied upon mesh supports; see page 10, lines 21-29. Murphy also discloses that any tissue type can be used to replace the corresponding tissue; see page 19, lines 7-17. In this way, Murphy provides a nexus from prior art constructs of Stoval to the use of the constructs disclosed therein that do not have exogenous support materials or synthetic materials.

Lambrecht teaches that it was known to repair both the opening the defect of the same disc during so as to render the claimed method *prima facie* obvious. Because of the new matter added to the claims, the Examiner asserts that the present claims have an effective filing date of October 25, 2007, which is the day that the amendment to the claims was filed.

Therefore, it is the Examiner's position that it would have been obvious to use the bioremodelable construct of Murphy as the graft implant material of Stoval for the same reasons that Murphy teaches using the same. And it would have been obvious to repair both the defect and the opening as taught by Lambrecht for the reasons that Lambrecht teaches doing the same.

With regard to the paragraph bridging pages 5 and 6 of the present specification, it is noted that MPEP 715 states:

> "Where applicant has clearly admitted on the record that subject matter relied on in the reference is prior art. In this case, that subject matter may be used as a basis for rejecting his or her claims and may not be overcome by an affidavit or declaration under 37 CFR 1.131. In re Hellsund, 474 F.2d 1307, 177 USPQ 170 (CCPA 1973); In re Garfinkel, 437 F.2d 1000, 168 USPQ 659 (CCPA 1971); In

re Blout, 333 F.2d 928, 142 USPQ 173 (CCPA 1964); In re Lopresti, 333 F.2d 932, 142 USPQ 177 (CCPA 1964)"

Regarding claim 3, since extracellular matrix is made of collagen, the same is present in the constructs of Stoval or Murphy.

Response to Arguments

Applicants' arguments filed October 25, 2007 have been fully considered but they are moot in view of the new grounds of rejection.

The Applicant argues that since Stoval makes no mention of extracellular matrix, it is not there; see page 6, second to last paragraph of the response. However, one of ordinary skill would understand that extracellular matrix forms in cell cultures for the cells utilized by Stoval. As was stated in the rejection, the presence of an extracellular matrix is inherently present in Stoval's material.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
Art Unit 3774